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Message Text

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ACTION NEA-10

INFO OCT-01 ISO-00 EB-07 COME-00 OES-06 HEW-04 CIAE-00

INR-07 NSAE-00 /035 W
---------- 100087
R 071127Z OCT 76
FM AMEMBASSY NEW DELHI
TO SECSTATE WASHDC 8835
INFO AMCONGEN BOMBAY
AMCONGEN CALCUTTA
AMCONGEN MADRAS

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E.O. 11652: N/A
TAGS: USINJC, EINV, IN, US
SUBJECT: PHARMACEUTICALS, STATUS REPORT

REF: NEW DELHI 13627

1) BEGIN SUMMARY. THE MINISTRY OF CHEMICALS AND FERTILIZERS (MCF) HAS REVIEWED THE HATHI COMMITTEE REPORT AND FORMULATED ITS RECOMMENDATIONS FOR SUBMISSION TO THE CABINET SUBCOMMITTEE. THE SUBCOMMITTEE HAS NOT MET FORMALLY TO REVIEW THE RECOMMENDATIONS, BUT THERE HAVE BEEN INFORMAL DISCUSSIONS BETWEEN HIGH-LEVEL OFFICIALS OF THE MCF AND THE MINISTRIES REPRESENTED ON THE SUBCOMMITTEE. IN OUR JUDGMENT, IT IS UNLIKELY THAT ANY POLICY WILL BE PRONOUNCED FOR THE INDUSTRY UNTIL AT LEAST THE BEGINNING OF THE NEXT SESSION OF PARLIAMENT ON OCTOBER 25. THE FOLLOWING IS THE STATUS OF THE MAJOR ISSUES. END SUMMARY.

2) PRICING. THE MCF CONSIDERED THE HATHI RECOMMENDATIONS INFLATIONRY. THE MCF RECOMMENDS THAT ALL BULK DRUGS PRODUCED LOCALLY BE UNDER PRICE CONTROL. IT RECOMMENDS A PROFITABILITY FORMULA OF 14 0/0 AFTER TAXES ON EQUITY PLUS RESERVES IN THE CASE OF PRODUCTS PRODUCED WITH INDIGENOUS TECHNOLOGY AND A 13 0/0 RETURN IN THE CASE OF IMPORTED TECHNOLOGY. WE UNDERSTAND THAT THIS FORMULA IS BASICALLY ACCEPTABLE TO THE MEMBERS OF OPPI. IT MAY NOT,
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HOWEVER, BE PRACTICAL TO DISTINGUISH BETWEEN SOURCES OF TECH-

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NOLOGY ON A GIVEN PRODUCT AND THEREFORE THE MINISTRY IS CONSID-
ERING ONE SINGLE PROFITABILITY PERCENTAGE. REGARDING FORMULA-
TIONS, THE MCF RECOMMENDS CONTROLS ON A SELECTIVE BASIS. IT RECOM-
MENDS NO INCREASE IN PRICES ON HIGHLY ESSENTIAL DRUGS, EXCEPT
WHEN BULK PRICES ARE REVISED AND RECOMMENDS A 75 0/0 MARK UP
LIMIT. FOR ESSENTIAL DRUGS, IT RECOMMENDS THAT PRICES BE
NEGOTIATED INDIVIDUALLY ON THE BASIS OF EXISTING PRICES AND THAT
THE MARK UP SHOULD NOT EXCEED 75 0/0. FOR BOTH BULK AND FORMULA-
TION PRODUCTION, IF RETURNS EXCEED THE STATED PERCENTAGES, THE
EXCESS IS TO BE USED FOR RESEARCH AND DEVELOPMENT. WE UNDERSTAND
THAT THE BUREAU OF INDUSTRIAL COSTS AND PRICES (BCIP) HAS
APPROVED ALL THE REDUCTIONS IN DRUG PRICES, BUT IS STILL CONSID-
ERING INCREASES IN PRICES. THUS, FIRMS WHICH HAVE HAD AN IN-
CREASE IN COSTS STILL REMAIN IN A STATE OF SQUEEZE. AMONG
THE 8 BULK DRUGS ON WHICH GOI HAS RECENTLY ANNOUNCED SUBSTANTIAL
PRICE REDUCTION (ABOVE 20 0/0) IS OXYTETRACYCLINE OF WHICH
PFIZER IS A MAJOR PRODUCER.

3) PRODUCTION. OE HATHI COMMITTEE RECOMMENDED THAT FOREIGN
FIRMS BE GIVEN APPROVAL FOR PRODUCTION IN EXCESS OF AUTHORIZED
CAPACITY ONLY WHEN THE DRUG WAS NOT MANUFACTURED OR PLANNED FOR
MANUFACTURE BY THE INDIAN PRIVATE OR PUBLIC SECTOR. THE MCF
RECOMMENDATION IS TO EXAMINE EACH CASE INDIVIDUALLY BEARING IN
MIND THE INTERESTS OF THE LOCAL SECTOR. FOR EXPANSION FOR THE
PRODUCTION OF BULK DRUGS BY FOREIGN FIRMS, THE MCF RECOMMENDED
APPROVAL IF 50 0/0 OF THE PRODUCTION IS MADE AVAILABLE TO LOCAL
FORMULATORS, WHICH WE REPORTED IN NEW DELHI 12425.

4) FERA GUIDELINES. AS A RESULT OF INFORMAL DISCUSSIONS BETWEEN
MCF AND OFFICIALS OF THE MOF, THE MCF HAS APPARENTLY TURNED
AROUND AND DECIDED THAT THE FOREIGN SECTOR SHOULD BE IN-
CLUDED IN THE FERA GUILDELINES. THUS, DRUG PRODUCTION WILL CON-
TINUE TO BE CONSIDERED HIGH TECHNOLOGY PRODUCTION. UNDER CON-
SIDERATION IS A REQUIREMENT THAT FOREIGN COMPANIES BE REQUIRED
TO PRODUCE BULK DRUGS AND FORMULATIONS IN A RATIO OF AT LEAST
ONE TO FIVE ACCORDING TO VALUE. THE MCF ENVISIONS THAT EVENTUALLY
MOST FOREIGN FIRMS WILL REDUCE THEIR EQUITY TO 51 0/0 IN ACCORDANCE
WITH THE RECENT AMENDMENT TO THE FERA GUIDELINES. THE HATHI
COMMITTEE RECOMMENDED AN IMMEDIATE REDUCTION TO 40 0/0 AND AN EVENTUAL

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REDUCTION TO 26 0"0 FOREIGN EQUITY. THUS, THE HATHI RECOMMENDATION
OF MINORITY SHARE HOLDING STATUS FORE FOREIGN FIRMS IS TURNED DOWN.
WE ALSO THINK THAT FOREIGN FIRMS WILL NOT BE PRESSED TO EXPORT
PHARMACEUTICALS TO THE SAME EXTENT FOREIGN MANUFACTURERS OF OTHER
PRODUCTS ARE BEING PRESSURED BY THE GOI.

5) AS WE PREVIOUSLY REPORTED, THE MINISTRY HAS TURNED DOWN THE
HATHI COMMITTEE RECOMMENDATIONS FOR NATIONALIZATION OF THE

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INDUSTRY, THE ELIMINATION OF BRAND NAMES, AND THE CREATION OF
A NATIONAL DRUG AUTHORITY.

6) WITH THE REMOVAL OF SETHI AND IN THE ABSENCE OF AN ACTIVE ROLE
BY MALAVIYA IN PHARMACEUTICALS, IT IS UNCLEAR WHEN THE GOI WILL
GIVE FORMAL APPROVAL TO THE DRUG POLICY. IF SETHI RETURNS,
WHICH IS UNLIKELY, OR MALAVIYA IS GIVEN THE MCF JOB FORMALLY,
THE MCF MAY PUSH FOR FORMAL APPROVAL. IN ANY EVENT, A FORMAL
POLICY PRONOUNCEMENT IS UNLIKELY BEFORE THE NEXT SESSION OF THE
PARLIAMENT WHICH BEGINS ON OCTOBER 25. THIS IS BECAUSE THE
PRINCIPALS INVOLVED ARE NOT LIKELY TO BE TOGETHER IN DELHI UNTIL
THAT TIME. THE POLICY DOES NOT HAVE TO BE APPROVED OR EVEN
ANNOUNCED IN PARLIAMENT, BUT COULD TAKE THE FORM OF ORDERS ISSUED
BY THE MCF ONCE THE CABINET SUBCOMMITTEE HAS GIVEN ITS FORMAL
APPROVAL.

7) IF THE DEPARTMENT, THE JOINT BUSINESS COUNCIL OR THE PMA HAVE
ANY DISCUSSIONS WITH GOI OFFICIALS ONPHARMACEUTICALS IN THE
NEAR FUTURE, LOCAL OPPI SUGGESTS THAT THE FOLLOWING POINTS COULD
BE MADE:
FIRST, IF A FOREIGN FIRM IS REQUIRED TO DILUTE, IT SHOULD BE
ALLOWED TO DO SOSLOWLY. ONE YEAR IS TOO SHORT A TIME PERIOD.
THREE YEARS WOULD BE MORE REASONABLE.
SECOND, FOREIGN FIRMS SHOULD NOT BE CONFIRMED TO PRODUCING ONLY
THE 41 ITEMS THAT THEY HAVE BEEN ASSIGNED. IF A FOREIGN FIRM
HAS THE TECHNOLOGY FOR PRODUCTION OF OTHER ITEMS, THIS SHOULD
BE ALLOWED WITH A SET-ASIDE FOR PRODUCTION OF THE PRODUCT BY
THE INDIAN PRIVATE/PUBLIC SECTOR.
THIRD, FOREIGN FIRMS SHOULD BE ALLOWED TO BRING IN NEWLY DEVELOP-
ED TECHNOLOGY TO PRODUCE BULK DRUGS. IF, FOR EXAMPLE, A COMPANY
REFINES ITS TECHNOLOGY ON A GIVEN PRODUCT, INDIA SHOULD BE
ALLOWED TO BENEFIT, WHICH IS NOT THE CASE AT THE MOMENT BECAUSE
IMPORTS OF TECHNOLOGY ARE CONFINED TO THE LIST OF 41 ITEMS.
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Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: DRUG INDUSTRY, INDUSTRIAL DEVELOPMENT, PROGRESS REPORTS
Control Number: n/a
Copy: SINGLE
Draft Date: 07 OCT 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: RELEASED
Disposition Approved on Date:
Disposition Authority: GolinoFR
Disposition Case Number: n/a
Disposition Comment: 25 YEAR REVIEW
Disposition Date: 28 MAY 2004
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976NEWDE14790
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760379-0325
From: NEW DELHI
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t19761073/aaaackuv.tel
Line Count: 155
Locator: TEXT ON-LINE, ON MICROFILM
Office: ACTION NEA
Original Classification: LIMITED OFFICIAL USE
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: LIMITED OFFICIAL USE
Previous Handling Restrictions: n/a
Reference: 76 NEW DELHI 13627
Review Action: RELEASED, APPROVED
Review Authority: GolinoFR
Review Comment: n/a
Review Content Flags:
Review Date: 14 JUN 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <14 JUN 2004 by buchant0>; APPROVED <14 JUN 2004 by GolinoFR>
Review Markings:

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US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: PHARMACEUTICALS, STATUS REPORT
TAGS: EINV, ECEM, US, IN, USINJC
To: STATE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006